Appendix Q. Comments on the Draft Multiple-Pesticide Sampling and Analysis Plan and DPR's Responses

From: <Chavira.Raymond@epamail.epa.gov>
To: <mbrattesani@cdpr.ca.gov>
Date: 5/31/00 7:25PM
Subject: Re: Fwd: RE: SAP

Madeline, here are my comments to the SAP (draft plan dated May 22, 2000).
Ray
[Note: DPR's responses to these comments are shown in italics.]

Review of Phase 2 Plan
General Comments

· All remedies as discussed at May 23 TAG meeting should be implemented prior to sampling. *Done when possible.*
· DPR should better describe how the analyte lists were determined. *Done.*
· Screening levels (acute, sub-chronic, and chronic) and Limits of Quantitation should be stated prior to sampling and included in Tables 1 & 2 (Exec Summary). DPR has had a year to develop these values. *DPR has revised the executive summary and the plan to include limits of quantitation. The plan includes preliminary screening levels, and a description of the process DPR toxicologists working with the TAG toxicologists will use to develop final health screening levels for acute, subchronic and chronic exposures.*
· Include an outline for assessing worst-case sub-chronic and chronic risk scenarios. *See Sections 2.2, 2.5, 2.6, and 8.*
· This plan was not subjected to external peer-review. A Project Plan peer-review would have added no more than $2,000 additional cost. *See later comment and response.*
· Delete all references to "comprehensiveness," since Table 1 & 2 target analytes (Exec Summary) will not be sampled contemporaneously. *Done.*
· Only three labs responded to DPR's "informal survey." There was no RFP Process. *References to Request for Proposal (RFP) process have been deleted.*

Although, Phase 2 was initially designed for comprehensiveness, it was scaled down as a result of state impediments in contracting outside the state. Note: At the June 1998 LIWG meeting DPR indicated its willingness to consider contracting outside for phase 2 however, claims of state impediments pertaining to contract procedures and labor interests have all but eliminated this possibility. This inability to go outside of California, has limited the TAG's ability to propose a scientifically defensible plan for phase 2 in which multiple analytical options could be considered. *Although state impediments to contract procedures did make contracting difficult during this process and may have limited options, DPR was able to contract with a lab outside of California that some members of the TAG recommended.*

EPA recommended to DPR that the Phase 2 plan be peer-reviewed. However, because the community member and some TAG members feel that we were left a "now or never" proposition and are reluctant to entertain a peer-review of the project plan as they feel it would delay the onset of sampling. *DPR considered U.S. EPA's recommendation. The TAG discussed this issue; the majority felt the peer-review was not necessary.*
DPR had only recently (May 2000) submitted a draft Phase 2 work plan to the TAG for review

(they have had funding since June 1999 and have had over a year to develop this plan). DPR has been slow to provide the TAG limited options. While most options suggested to DPR by the TAG have not been taken on the whole [sic]. *DPR received funding in July 1999 and began discussions with the TAG about its recommendations for this project that same month. In fall 1999, DPR provided the TAG data quality objectives for its review and continued discussing options related to sampling and analysis. DPR considered all the TAG's suggestions and developed a sampling and analysis plan that the majority of TAG members agreed was acceptable.*

Since the TAG was provided only one viable proposal, this limited the options the TAG could consider.

Table 1 & 2 (Exec Summary) target analytes will not be sampled contemporaneously goes to comprehensiveness and exposure to multiple chemicals.

In November 1999, DPR made a public commitment to the meteorological study and after a rather difficult process, negotiated a contract with the City of Lompoc. This delay has resulted in the air and met studies to occur at different times, contrary to the LIWG recommendation. *The delays were unexpected and unavoidable. DPR also regrets that the pesticide air monitoring and meteorology studies occur at different times.*

An analysis for TICs [tentatively identified compounds] was rejected based on the assumption that standards do not exist for all pesticides. This is incorrect; standards can be either purchased through Chemserve or other vendors. S*tandards do exist; however, we would have to obtain several hundred standards or more to identify all the potential compounds that may be tentatively identified (e.g., pesticides as well as compounds other than pesticides).*

Of the options the LC/MS will allow for the carbamates and other neutral or thermally labile compounds that cannot be analyzed for by GC.

<u>Additional Comments/Questions</u>

What is the primary question DPR is trying to answer? *See Section 2.1.* It appears that fiscal rather than technical constraints are the underlying factor (based on only one lab's estimate) for which the TAG is to make its decisions. *DPR and the TAG considered a variety of approaches and options in this sampling and analysis plan. This final plan is a product of balancing fiscal and technical constraints while providing a study design that is appropriate to answer the following three questions: (1) Are Lompoc residents exposed to pesticides in air? (2) If so, which pesticides and in what amounts? (3) Do these levels exceed human health standards?*

Can this Plan meet the study goals and data quality objectives? *Yes.*

If a risk assessment is conducted, is the generation of 10-12 weeks of data adequate to meet the goals, i.e. sub-chronic, chronic exposure scenarios? What specific models would DPR use to assess pesticide levels outside the sampling period? Will 10 weeks of sampling data meet the

data objectives? *DPR is not doing a formal risk assessment. However, the ten weeks of sampling will be sufficient to permit comparisons with screening levels.*

Would DPR consider measured levels to be the actual exposure experienced by the residential population? Inside/outside penetration, children playing, etc. How representative would these measurements be? *DPR considers community outdoor air monitoring the most effective way to quantify the town's exposure to pesticides. At tis January 2000 meeting, the LIWG reviewed this issue and concurred. Other types of monitoring, such as indoor air, partitioning dust/air, partitioning fog/air, and targeted monitoring near field applications, were all considered. However, these other types of monitoring are related to more specific exposures. If warranted, based on results from this sampling and analysis, other types of monitoring could be conducted at a later date.*

What analysis will DPR conduct to characterize exposure? *See Sections 2.2, 2.5, 2.6 and 8.*

<u>Data Collection</u>

· Limited No. of analytes (comprehensive?). *Deleted references to comprehensive.*
· Lack of risk-based prioritization. DPR should determine which pesticides have the potential to contribute to the greatest risk. *DPR, in consultation with the TAG, did determine which pesticides have the potential to contribute the greatest risk. See Appendix B for a detailed description of this process.*

DPR need to analyze and quantify the No. of residents likely to be exposed and the No. of residents near fields. Which areas are impacted more than others? *No, because the plan to analyze for pesticides in Lompoc does not have a demographic characterization of the residents proximal or distal from the sites of application. Once the sampling data have been collected and summarized, it may be possible to develop, if the funds are available, a spatial description of relative risks related to pesticide exposures. In addition, these data will be forwarded to the LIWG's Health Issues' Subgroup that may develop such a spatial description.*

Will DPR use MOE's for people living near fields similar to MB, MITC RCDs? *DPR will calculate MOE's based on measured air levels.*

Has DPR accounted for the sensitive populations in the design? Near fields? *Sensitive populations are taken into account, to some extent, in the application of uncertainty factors when the health screening levels are developed. To account for sensitive populations more fully would require a house-to-house survey of the population for their demographic characteristics. This would include a health survey, characterization of the ages, activity patterns (time inside vs. outside), place of employment (Lompoc or elsewhere), perhaps socioeconomic status, residence characteristics, and any other factors that might affect their sensitivity to pesticides in the ambient air. This type of characterization of the residents in Lompoc was not a part of the original plan; therefore, to do this type of analysis would require additional funding.*

DPR should in their analysis quantify the No. and distribution of residents potentially exposed to OPs together? *This is certainly potentially feasible but it seems important to follow the lead of the U.S. EPA who is developing scenarios to consider aggregate and*

cumulative exposures to organophosphate (OP) insecticides. It would not be prudent for the TAG to develop a cumulative/aggregate exposure scenario analysis for the OP insecticides until the U.S. EPA has completed their process for this class of pesticides.
Other analytes? *Until the U.S. EPA develops their aggregate/cumulative process for the OP insecticides which clearly have the same mode of action, it would not be technically defensible to develop a process to consider other classes of pesticides whose common mode of action is less well-defined and understood.*

Chronic scenario relevant given that some segment of population has resided in Lompoc at least 30 years. *The plan includes a chronic scenario.*

What degree of confidence does DPR have in this design to collect those pesticides that pose the greatest risk to the community? *DPR has confidence in the design to collect data for those pesticides for which we monitor; however, we obviously won't collect data for pesticides for which we do not sample. We were not able to sample for all the pesticides the TAG prioritized due to constraints of the study, e.g., maneb. Although the TAG prioritized maneb due to its toxicity, analytical methods are very costly. The TAG discussed this issue and the TAG's consensus was that this plan still provided an appropriate study design.*

UCD Proposal (see Appendix J)
Specific Comments to UCD Proposal

· UCD does not have the capacity to do all target analytes as agreed upon by the TAG and DPR. *That is correct; however, they do have the capacity to analyze up to 23 pesticide active ingredients and 5 breakdown products.*
· Although the estimate costs per sample are reasonable they are significantly higher than the work done for Phase 1. Please breakdown the cost estimates from UCD. The cost significantly differ [sic] from the Phase 1 study? *This issue is outside the scope of the sampling and analysis plan.*
· Why are ODM-oxon, dichlorvos, and disulfoton excluded? ODM now as separate analysis for a limited two-week period. *Oxydemeton-methyl (ODM) oxon was not excluded. It does not exist as a separate breakdown, but is formed during the analysis in which oxydemeton-methyl is oxidized and converted to oxydemeton-methyl oxon. Dichlorvos (DDVP) is included. Disulfoton is excluded because it can only be analyzed by a single method. To do this analysis would have significantly added to the cost of the project and DPR decided to analyze for as many of the compounds as possible with the funds available.*
· Many of these compounds listed in Table 1 were done by Majewski et al. This approach was not pursued. *DPR considered this approach, but we did not choose this option due to its higher cost (all method development would have to be repeated, all trapping efficiency would have to be repeated, cost/sample much higher due to using high volume samples, and it would have delayed the start of sampling). With the option in this plan, we are able to achieve all target detection limits using the low-volume samplers.*
· To determine extent of breakthrough, trapping efficiency studies should be conducted at the high end sampling rate of 50 L/min corresponding to approximately 72 m^3 of air over a 24-h period (as opposed to 30 L/min). *The field sampling rate is 15 L/min; data show that 30 L/min*

(twice the field rate) is adequate to determine the extent of breakthough in the trapping efficiency studies (see Table 17). In addition trapping over at least two temperature and RH extremes would be useful. Also, spike at two rather than one level. *Although this would be useful information, funds limited the data we could collect.*

· All methods developed should be field tested and subject to performance evaluation audit samples. The UCD modified phase 1 method has yet to be field tested. *The trapping efficiency tests fulfill the field testing.*

· Using only resin material without a pre-filter may miss those pesticides which are particulate-associated such as permethrin. Particles could channel through the sorbent matrix. And since it is difficult to create an aerosol atmosphere the filter should be added and combined with the resin during extraction. *This sampling and analysis does not address this component. However, although the sample analysis does not account for all the particulate, DPR believes that the fraction we may be missing is a small percentage. Samples for particulates may be collected to estimate the missing fraction.*

· Evaporating to dryness on a rotovap may lead to loss of the more volatile compounds. *Noted. This information has been forwarded to the UCD lab.*

· Not clear whether a volume of 2 or 4 ml will be used. *A 4 ml volume will be used.*

· Drying of resin in a vacuum oven is preferred over a hood since the resin may pick up lab chemicals leading to resin contamination and subsequent interferences. *Noted. Comment forwarded to the UCD lab.*

· XAD-4 may be best for OPs but premature to determine adequacy for other target analytes and their breakdown products. *Method development will determine adequacy of XAD-4 resin for other target analytes.*

· Confirmation policy needs to presented in the plan. *The plan now includes the confirmation policy (Section 7.4). For the organophosphates, we will confirm a sample whose concentration is more than 5 times the estimated quantitation limit (EQL). (Note: Mass spectroscopy is used to confirm and its method detection limit is 5 times the EQL.) If no sample concentrations exceed this level, we will attempt to confirm 10% of the positive samples.*

From: "Harnly, Martha (DHS-EHIB)" <MHarnly@dhs.ca.gov
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Date: 5/18/00 2:16PM
Subject: RE: Comments on MP-SAP

To my previous comments on the Lompoc Air Monitoring protocol, I add the following, mostly editorial, comments:
[Note: DPR's responses are shown in italics.]

Executive Summary
In the Executive summary and the Background of the SAP there needs to be a clear summary statement of the differences between Phase I and Phase II. That summary statement should answer the question: What more will Phase II provide? *Done.*

I would make the following additions for the lay reader.
Define subchronic and chronic. *Done.*
Describe the measurement of particulates and whether Tentatively Identified Compounds (TICs) will be attempted. *Done.*
I prefer the term "health protective" to "conservative"
Insert "legal" to "not health standards" *Done.*

SAP
Background (page 5), 1st paragraph. This paragraph has always bothered me. I think it sets the sampling up to do something it cannot do. I would prefer it to read: "... (first voice in 1992) about potential exposure from drift of pesticides during and following agricultural applications. To evaluate these concerns, information on the levels and amount of pesticides to which people may be exposed are required." *Revised as suggested.*

Page 8 and Table 5. Bottom of page 8 indicates that (c) regulatory action is taken. Yet, Table 5 describes no scenario that DPR would consider a health concern and take action based solely on the results. Is there any level of any thing that could be detected that DPR would take action on, without first conducting a "more refined analysis" or first taking more measurements? If there is, what is it???????? *Yes, there are levels that could be detected that may trigger DPR to take action. Reworded Section 2.5 and Table 8 to clarify.*

Page 10: Study boundaries seems like a real misfit as a heading. I would suggest "Study Design". Describe the measurement status of particulates and whether TICs will be attempted. The LIWG is clearly interested in particulates and because of cycloate, TICs are on our minds. *Done.*

Page 13: You need more detail (an appendix would be great) on the basis for the statement "certain breakdown products, adjuvants, inert ingredients, etc. might pose an equal or greater health risk." *We deleted the sentence.*

Page 25: It would be really nice if the units on page 25-26 were the same as the Phase I results.

Revised.

5/23/00 One more editorial comment. In the section on pesticide air sampling in other areas of CA, “urban background” levels are reported. It would be nice to know whether urban background is ag urban, e.g., Fresno or urban urban, e.g., San Francisco. *Revised. The urban background sites we use for ambient monitoring studies are always the largest urban area in the county of monitoring (e.g., Fresno when in Fresno County).*

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Date: 5/23/00 11:44AM
Subject: RE: Executive Summary

Madeline, my comments follow:
[Note: DPR's responses are shown in italics.]

The sampling plan should include a description of the subchronic period as 14-day, rather than "k-day." *Done.*

A brief discussion should be included which notes that the risk assessment will include summation of risks across chemicals. Cancer risks should be summed. Noncancer risks should be summed using the hazard index/quotient approach (summing the intake/RfD quotient across chemicals which have similar target organs to develop a hazard index by target organ). The target organs to consider include CNS, liver, kidney, thyroid, GI. Also important are the repro/developmental toxin indices and endocrine disruptors. If cholinesterase inhibitors are summed, there should be no separation of plasma from brain cholinesterase inhibition. *Done. See Section 2.1.*